# PSJ3

# Exhibit 40

**From:** Sarah Rubenstein
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**CC:** David Duvall
**Sent:** 3/16/2001 4:49:26 PM
**Subject:** Fwd: Notes from Experts Meeting
**Attachments:** Notes from Experts Meeting

Discovery International

# Memorandum

**To:** Jim Witt, Dennis Fitzgerald, and the Duragesic Team

**From:** David Duvall

cc. Christine DeVries, Ed Rady, Sarah Rubenstein

**Date:** {AUTODATE}

**Re:** Notes from Janssen's Experts Meeting in Phoenix, AZ

Thank you for including us in the Experts Meeting. It was an excellent opportunity for us to gain further insights on the challenges and opportunities with Duragesic. This memo reflects our collective observations and broad recommendations based on what we learned. More detailed descriptions of our recommendations will follow shortly but we wanted to share our topline thoughts as well.

**General Meeting Observations**

The Award ceremony and Jim Eckhardt's opening set a very positive and professional tone for the meeting. The meeting was generally well organized; the poster on a key topic outside the room was creative; the faculty was strong and prestigious.

Opportunities going forward – General Comments

- Survey the participants ahead of the program to ensure the content is finely honed and modified to meet their current needs, e.g., was the *neurobiology of addiction* lecture on target and a good use of time? Share the survey results at the beginning of the program and tie the results to the program objectives

- A baseline knowledge and needs assessment survey should be conducted at start using keypad responses, and repeated at conclusion of meeting to determine learning. It would be useful to know how many of physicians had attended previous meetings. This will also dictate how much review information is needed in the program.

- The audience (potential speakers) should view/hear presentations of the official slide set and discussion of the notes pages as they follow along. The common questions that might occur in reaction to the slides should be answered and discussed.

- Talks could be more interactive throughout. In fact, typical audience questions to each slide could be presented for keypad response, leading to a discussion of the "right" answers.

- The question cards should be collected and summarized, submitted to the appropriate faculty for response, and responses sent to all attendees. There was not nearly enough time for questions.

- Recommend using one floor microphone for each aisle at the front of the room. Some of the speakers were not loud enough when they turned away from the podium to look at their slides. We suggest using a lavalier along with the podium microphone.

Opportunities going forward – Speaker Management and Presentations

- Add a legal/regulatory talk as part of future programming. (We recognize this is normally done but not clear why is was not done here)

- Important to profile ALL of the Duragesic KOLs. A password-protected database of speakers could be created with their ranking as national, regional, or local speakers. We must develop profiles, criteria, and nomenclature (e.g., Elite, National, Regional, and Local) etc. and then subcategories of Steering Committee Member, Speakers Bureau member, etc. to better enable us to target, follow-up and utilize the KOLs. This could mitigate some of the frustration I sensed among the Duragesic team members regarding the attendees.

- Potential speakers should be profiled for different uses based on criteria that establish them as a national, regional, or local authority, what areas they address best, and then used as a resource for speaking on those topics at that level. Speakers should be asked only to give presentations at their proper level; invitations to speak and acceptances should be entered to prevent overbooking, and their audience evaluations posted.

- All potential members of the Speakers Bureau should anticipate that they come to the meeting prepared to commit to conducting a certain number of sessions per year as part of an integrated campaign. Related to the above point, a better job could be done articulating the expectations of the participants and the systems in place to support and coordinate their efforts throughout the year.

- Many slides need to be re-done. The Power Point ability to build slides, using color and timing would make many anatomical and physiological processes much more accessible. The price of entrance as a faculty member MUST be their willingness to accept assistance reviewing and re-doing (as necessary) slides that are not legible. It is simply not fair to the 150 experts and educators in the audience to have to suffer through overly complex or illegible slides.

Opportunities going forward – Content

*Decade of Pain Control and Research*

- There is a real opportunity to leverage "Decade of Pain Control and Research" recently introduced by congress, which could provide the focus of a large national educational (CME) initiative on pain, directed to a variety of target audiences, including pain specialists, primary care physicians, oncologists, palliative care professionals, nurses, pharmacists, policy-makers and state medical societies.

*Mechanism Story*

- Take advantage of the opportunity to differentiate Duragesic through mechanism. "An opioid is not an opioid." Genetics plays a big role in determining opioid efficacy. This mechanism approach would only be applicable to opinion leader faculty, since most MDs don't care about mechanism, and it's too complex for them. But, there is a big win for the KOLs to understand the differentiation, the best way is to focus on them one on one. We need to put together our story, and then take it to them. Once we get a core of 15 to 20 KOLs agreeing, then we can roll it out.

*Abuse/Addiction Story*

- There was a lot of discussion around the 6% of patients being vulnerable to addiction. Recommend publications on this issue, a "mini" pub plan that PR could pick up on, and serve to balance out the negative press. A primer is needed on the complete documented facts on opioid use and abuse. A heavily referenced editorial effort here would provide an in-depth review presentation. This would be an opportunity for John Coleman to talk on his research.

*Regulatory Issues*

- The '98 Model Guidelines are woefully under-recognized and followed. Much of this has to do with state legislation and policy driven by state medical boards. According to Gilson, only 15 states comply partially and 7 states comply fully. According to Brookhoff, if one were to generalize, the medical boards are comprised of physicians that are near the end of their career and/or have some political connection to the governor or state senator.

- We need to consider targeting state medical boards as part of our Decade of Pain Control National Initiative with a uniform message) about the emerging medical opinion on the appropriate role of LA opioids for chronic pain. We should consider working with and through the Federation of State Medical Boards. An independent Pain Management and Policy Summit is one approach (wherein we could deliver a clinical update based on the National CME Core Curriculum we'll be developing)

- And/or we should overlay the market potential with the states that are non-compliant or need the most education and develop a targeted plan for reaching them. Per Brookhoff, Dr. Joranson from Wisconsin "went on a road show last year" but he did not know to what states and what the format of the show was. We need to research this.

- JCAHO guidelines must be boiled down to a very practical level for physicians, and representatives need educational tools to help teach and reinforce the guideline to physicians in their territories.

**Other Comments and Observations**

*Education*

- Kathleen Foley's message was quite clear and simple and one that we can rally around: "The future is in professional education, public education, and patient advocacy." In discussion of the current drivers of pain management, the JCAHO standards and Robert Wood Johnson Foundation were referenced frequently by Dr. Foley. We should follow up with her re her thoughts on future initiatives, as she is tied into the various organizations. Her recommendations for focus are the

State Pain Initiatives, the End of Life Care Task Force, the AMA's EPEC program, EPERC, and the ELNEC nursing program which Betty Farrell heads up. FYI, DI has worked with Betty on several occasions. She's tops for nursing and pain.

- Per Dr. Foley, "we need to speak with ONE VOICE." This point is driven home when we look at the detailing message variability vs. Purdue. Granted, this is not a direct measure of our central activity; however, it does paint a picture of what messages are being left in the minds of physicians.

- According to Dr. Foley, approximately 1400 MDs are certified as pain management specialists through the American Board of Pain Management. Steve Passik suggested that there is an opportunity is to get out and "model" how to practice pain management. He believes the best way to do this is to develop a structured way to go to the physicians' practices and work with them for a day or two. This could be an interesting opportunity for Janssen if we can develop a cost-effective and efficient way to make this work, such as a "Practice Modeling" preceptorship program with eventual certification.

*Clinical Trials*

- The clinical trial talks could have been used as an opportunity to establish a new positioning for Duragesic, given the new research. Discussing how the 12.5 µg patch will be used for non-malignant pain and initial long-acting therapy would have been good.

*Dosing, Titration, Switching*

- The dosing and titration issues are important barriers to use. The KOLs' recommendations are very important, and we need to focus much more on them. The self-confidence of these experts on adjusting dosing and titration schedules is a critical message to get to all physicians. Dose conversion is poorly understood and perceived as complicated. Recommend a CD-ROM or web-based schedule to address this need, an automated calculator. Dosing, titration, and switching guidelines should also be incorporated in CME programs.

- A real need in this area is algorithm for care AND reimbursement. Major barriers to opioid use in chronic pain are 1) fear of regulatory barriers or authorities, 2) competition with other specialists, and 3) competition with other "unproven" treatments. CME activities can address these issues.

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